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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,929	09/25/2003	Brian B. Lentricchia	2024738-2247387008 (11.02)	8293
38732	7590	02/07/2006	EXAMINER	
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,929

Applicant(s)

LENTRICHIA ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 1/24/06. Claims 4-13, 19-32 have been canceled. Claims 1-3, and 14-18 are pending.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3, 14-18 are rejected under 35 U.S.C. 112, second paragraph for reasons of record advanced in the previous Office Action mailed 10/24/2005. Applicants argue that the limitations of “examining said collected material” would be familiar to an ordinary skill in the art and specification on page 5, lines 1-4 describes the two such method. Applicants additionally assert that the claims are complete and no additional steps are needed. Applicant’s argument as part of amendment filed 1/24/06 has been considered fully, but they are not persuasive.

Applicants are reminded that, although, the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, there is a vast difference between looking at cells under a microscope and Hybrid Capture which Applicants have not taught or possessed at the time of filing. One needs a whole host of other essential elements to detect a virus, i.e.,

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specific probes, which simple filtration does not provide. Listing the broad names of well known techniques does not make the claims definite. The claims have to be interpreted in light of the specification and since the specification does not set forth how the detections to occur the claims are vague, confusing, and indefinite. Simple place of cells under a normal microscope would not reveal virus-infected cells. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 112

Claims 1-3, and 14-18 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 10/24/2005. Applicants argue that it appears the examiner does not understand the purpose of the Applicant's disclosure. Applicants further assert that ordinary skill in the art would certainly be able to practice the invention absent undue experimentation. Applicants assert the filtration of system now claimed would allow a practitioner to answer the questions raised by the Office. Applicant's argument as part of amendment filed 1/24/06 has been considered fully, but they are not persuasive. First, Office has full understanding of the claimed invention. Simple filtration technique is not difficult of a concept to understand. However, translating the simple filtration into detection for all types of viruses is at best a huge leap, which if Applicants have no appreciation for Office certainly does (emphasis added). The limited teaching that is provided in the disclosure would not be helpful to an ordinary skill in the art, and would force an ordinary skill in the art to conduct large quantity of experimentation. Applicants cannot expect others to enable their invention while they obtain exclusive patent term. The entire teaching in this case is directed to simple filtration of cells that are supposedly infected with virus. This, however, does not add anything to detection or analysis

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of how to detect or analyze the virus infected cells (emphasis added). How does utilization of cell filtration relate to detection or analysis of infected virus? The claims are directed to method of analyzing biological sample to detect virus, but the teaching is directed to isolation of cells on filters. There is a vast difference between the two. Method of isolating cells on filter is not the same as detecting a particular virus or virus in general. The field of virus detection is unpredictable (emphasis added), as Applicants own disclosure is tantamount to the unpredictability of the field. In an unpredictable field the disclosure must provide teaching so one of ordinary skill in the art can practice the invention absent undue experimentation. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 1-3, 14-18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ferguson Gary (US Patent No. 6,905,594 B2), for reasons of record advanced in the previous Office Action mailed 10/24/2005. Applicants argue that Ferguson patent does not contemplate a method for the separation of viral particles from cells. Applicant's argument as part of amendment filed 1/24/06 has been considered fully, but they are not persuasive. Applicants' understanding of their own invention is rather misplaced. The claimed invention is not about separating virus particles from cells. The claims are directed to filtration of cells infected with virus (emphasis added). There is a huge difference between separating virus and separating cells infected with a virus. For example, claim 1 last sentence reads as following: "examining said collected material to determine if HPV infected cells are present." The invention is directed to separation of virus infected cells, not virus per se. Ferguson taught a method of capturing materials suspended in a liquid utilizing

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a filter apparatus (see the abstract and all the claims). They also taught suspended materials can be viruses (see column 1, lines 18-28). Moreover, Ferguson taught the captured material can be analyzed such as visualization (see column 1, lines 29-32, and column 5, lines 1-5, column 8, lines 58-62). As stated before the pore size is a design choice unless the proof of criticality is proven. The differences are within the purview of one ordinary skill in the art. The above cited patent is a pioneering invention and is entitled to broad interpretation. The rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 1-3, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Radcliffe et al (US patent no. 5,942,700) for reasons of record advanced in the previous Office Action mailed 10/24/2005. Applicants argue that Ferguson patent does not contemplate a method for the separation of viral particles from cells. Applicant's argument as part of amendment filed 1/24/06 has been considered fully, but they are not persuasive. As stated above Applicants' have misinterpreted their claimed invention. The claimed invention is not about separating virus particles from cells. The claims are directed to filtration of cells infected with virus (emphasis added). There is a difference between separating virus and separating cells infected with a virus. For example, claim 1 last sentence reads as following: "examining said collected material to **determine if HPV infected cells** are present", also look at the preamble of the independent claims, "detect cells infected by HPV, or detect cells infected by virus." The invention is directed to separation of virus infected cells, not virus per se. Radcliffe et al taught a method of collecting samples including biological samples through a filter wherein the particles can be

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further analyzed (see the claims, the abstract, and column 4, lines 55-57). The recitation of biological sample broadly incorporates virus, and papillomavirus. Additionally, they taught the filter size (see column 2, lines 44-50).

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

02/03/2006


ALI R. SALIMI
PRIMARY EXAMINER